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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Fallaux et al.

**Serial No.:** To be assigned

**Filed:** July 19, 1999

**For:** PACKAGING SYSTEMS FOR  
HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

**Examiner:** To be assigned

**Group Art Unit:** To be assigned

**Attorney Docket No.:** 3935US

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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

DOCUMENTSU.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
5,378,618	01/03/95	Sternberg et al.
5,545,522	08/13/96	Van Gelder et al.
5,652,224	07/29/97	Wilson et al.
5,670,488	09/23/97	Gregory et al.
5,707,618	01/13/98	Armentano et al.
5,753,500	05/19/98	Shenk et al.

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Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
· WO 94/23582	10/27/94	PCT
· WO 94/26914	11/24/94	PCT
· WO 94/28152	12/08/94	PCT
· WO 95/00655	01/05/95	PCT
· WO 95/02697	01/26/95	PCT
· 95201611.1	06/15/95	EP
· 95201728.3	06/26/95	EP
· WO 95/27071	10/12/95	PCT
· WO 96/16676	06/06/96	PCT
· WO 96/18418	06/20/96	PCT

WO 96/33280	10/24/96	PCT
WO 96/40955	12/19/96	PCT
WO 97/00326	01/03/97	PCT
WO 97/00947	01/09/97	PCT
WO 97/04119	02/06/97	PCT
WO 97/05255	02/13/97	PCT

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Other Documents

- Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", Proc. Natl. Acad. Sci. USA, 93:3352-3356, April 1996.
- Amalfitano et al., "Isolation and characterization of packaging cell lines that coexpress the adenovirus E1, DNA polymerase, and preterminal proteins: implications for gene therapy", Gene Therapy, 4:258-263, 1997.
- Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", Human Gene Therapy, 6:1343-1353, October 1995.
- Brough et al., "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 70(9):6497-6501, September 1996.
- Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", Virology, 190:624-634, 1992.
- Brough et al., "Stable Cell Lines for Complementation of Adenovirus Early Regions E1, E2A and E4; Abstract Book CSH Conference On Gene Therapy, 42, 1996.
- Caravokyri et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5", Journal of Virology, 69(11):6627-6633, November 1995.

Fallaux et al., "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors", Human Gene Therapy, 7:215-222, 1996.

Fisher et al., "Recombinant Adenovirus Deleted of All Viral Genes for Gene Therapy of Cystic Fibrosis", Virology, 217:11-22, 1996.

Gao et al., "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", Journal of Virology, 70(12):8934-8943, December 1996.

Gorziglia et al., "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", Journal of Virology, 70(6):4173-4178, June 1996.

Hardy et al., "Construction of Adenovirus Vectors through Cre-lox Recombination", Journal of Virology, 71(3):1842-1849, March 1997.

Hehir et al., "Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications To Prevent Their Occurrence", Journal of Virology, 70(12):8459-8467, December 1996.

Imler et al., "Novel complementation cell lines derived from human lung carcinoma A549 cells support the growth of E1-deleted adenovirus vectors", Gene Therapy, 3:75-84, 1996.

Kornberg, Arthur, "DNA Replication", W.H. Freeman and Company, San Francisco, 4 pages (double sided).

Krougliak et al., "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", Human Gene Therapy, 6:1575-1586, December 1995.

Lieber et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo", Journal of Virology, 70:8944-8960, December 1996.

Ngo et al., "in The Protein Folding Problem and Tertiary Structure Prediction", Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, 1994.

Sabatie et al., "Process Development for the Production of Second Generation Adenovirus Vectors for Gene Transfer in Clinical Protocols", Abstract Book 14th Meeting on Animal Cell Technology, BI-3, 1996.

Schaack et al., "Adenovirus Type 5 Precursor Terminal Protein-Expressing 293 and HeLa Cell Lines", Journal of Virology, 69(7):4079-4085, July 1995.

Vanhaesebroeck et al., "Modulation of Cellular Susceptibility to the Cytotoxic/Cytostatic Action of Tumor Necrosis Factor by Adenovirus E1 Gene Expression is Cell Type-Dependent", Virology, 176(2), pp. 362-368, June 1990.

Wang et al., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions", Gene Therapy, 2:775-783, 1995.

Yeh et al., "Efficient Dual Transcomplementation of Adenovirus E1 and E4 Regions from a 293-Derived Cell Line Expressing a Minimal E4 Functional Unit", Journal of Virology, 70(1):559-565, January 1996.

Zhou et al., "Development of a Complementing Cell Line and a System for Construction of Adenovirus Vectors with E1 and E2a Deleted", Journal of Virology, 70(1):7030-7038, October 1996.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventor:

Serial No.: 08/515,495

Filed: August 15, 1995

For: RECOMBINANT VECTORS DERIVED FROM ADENOVIRUS FOR USE IN GENE THERAPY

Serial No.: 08/820,479

Filed: March 18, 1997

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS

Serial No.: 08/793,170

Filed: March 25, 1997

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 08/892,873

Filed: July 15, 1997

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 08/930,094

Filed: December 15, 1997

For: RECOMBINANT VECTORS DERIVED FROM ADENOVIRUS FOR USE IN  
GENE THERAPY

Serial No.: 09/000,133

Filed: February 24, 1998

For: METHOD AND MEANS FOR TARGETED GENE DELIVERY

Serial No.: 09/065,752

Filed: April 24, 1998

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

Serial No.: 09/077,444

Filed: May 29, 1998

For: REGULATED PROTEIN EXPRESSION IN STABLY TRANSFECTED  
MAMMALIAN CELLS

Serial No.: 09/097,239

Filed: June 12, 1998

For: HIGH THROUGHPUT SCREENING OF GENE FUNCTION USING AV  
LIBRARIES FOR FUNCTIONAL GENOMICS APPLICATIONS

Serial No.: 09/298,745

Filed: April 23, 1999

For: MEANS AND METHODS FOR NUCLEIC ACID DELIVERY VEHICLE  
DESIGN AND NUCLEIC ACID TRANSFER

Serial No.: 09/317,062

Filed: May 7, 1999

For: VECTORS AND METHODS FOR PROVIDING CELLS WITH  
ADDITIONAL NUCLEIC ACID MATERIAL INTEGRATED IN THE  
GENOME OF SAID CELLS

Serial No.: 09/332,803

Filed: June 14, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

Serial No.: 09/333,820

Filed: June 15, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

Serial No.: 09/334,765

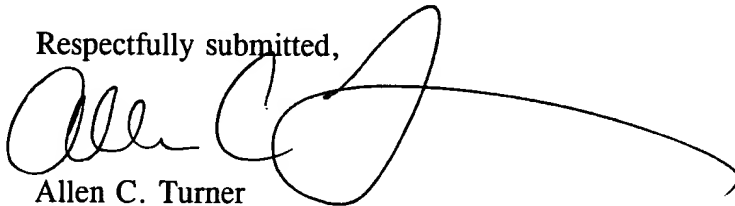
Filed: June 16, 1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. 1.17(p) is required.

Respectfully submitted,



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Enclosure: Form PTO-1449  
Copy of documents cited